

REMARKS

Reconsideration and allowance of the subject application are respectfully requested.

Claims 1, 2, 4-9, 11-13 and 15-26 are pending in the application.

Basis for new claim 26 can be found in the present specification, including at pending claim 1 and page 22, line 31 through page 23, line 6. Basis for new claims 27-30 can be found at original claims 12, 17 and 18, including their base claims, and at page 22, line 31 through page 23, line 6 of the present specification. No new matter has been added.

The rejection of claims 12, 17 and 18 under 35 U.S.C. § 112 on page 8, paragraph No. 7 of the Office Action, is obviated by the cancellation of claims 12, 17 and 18 set forth above. Accordingly, withdrawal of the Section 112 rejection is respectfully requested.

The rejection of claims 1, 2, 4-9, 11, 12, 17, 19 and 20 under 35 U.S.C. § 102(b) over McClelland is respectfully traversed. Claims 1, 2, 4-9, 11, 12, 17, 19 and 20 are not anticipated by McClelland for the many reasons of record and for the following reasons.

The particles produced by McClelland use the polymer as matrix forming material in the particles themselves. To form the matrix, the polymer particles are brought in contact using extrusion forces to form a network (coherent polymer phase).

In contrast, in the claimed invention, the polymer particles are entrapped inside a matrix of excipient. The polymer particles are not coherent since they are separated by excipient. Independent claims 1, 2, 19, and 20, and the claims dependent thereon, specifically recites that the matrix material is "incoherent," which distinguishes them from McClelland.

not coherent

For these reasons, McClelland cannot anticipate the claimed invention. Accordingly, withdrawal of the Section 102 rejection is respectfully requested.

The rejection of claims 1, 2, 5-9, 11, 12 and 17-20 under 35 U.S.C. § 102(e) over Sparks is respectfully traversed. Claims 1, 2, 5-9, 11, 12 and 17-20 are not anticipated by Sparks for the many reasons of record and for the following reasons.

In the claimed invention, the polymer particles are entrapped inside a matrix of excipient. The polymer particles are not coherent since they are separated by excipient. Independent claims 1, 2, 19, and 20, and the claims dependent thereon, specifically recites that the matrix material is "incoherent," which distinguishes them from Sparks.

For these reasons, Sparks cannot anticipate the claimed invention. Accordingly, withdrawal of the Section 102 rejection is respectfully requested.

The rejection of claims 1, 2, 5-9, 11, 12, and 17-20 under 35 U.S.C. § 102(e) over Motta is respectfully traversed. Claims 1, 2, 5-9, 11, 12, and 17-20 are not anticipated by Motta for the many reasons of record and for the following reasons.

In the claimed invention, the polymer particles are entrapped inside a matrix of excipient. The polymer particles are not coherent since they are separated by excipient. Independent claims 1, 2, 19, and 20, and the claims dependent thereon, specifically recites that the matrix material is "incoherent," which distinguishes them from Motta. When Motta refers to "excipient," he really means matrix since his excipient is a polymer. See claim 4 of Motta. Thus, as noted by the Examiner on page 6, last paragraph of the Office Action, Motta's excipient (really matrix) is "coherent" with the drug. Thus, Motta teaches away from the claimed invention.

*Allegation
Example 1
has no polymers*

For these reasons, Motta cannot anticipate the claimed invention. Accordingly, withdrawal of the Section 102 rejection is respectfully requested.

The rejection of claims 1, 2, 4-9, 11-13, 15-20 and 23-25 under 35 U.S.C. § 102(e) as being anticipated by Norling is respectfully traversed. The rejection of claims 1, 2, 4-9, 11-13, and 15-25 under 35 U.S.C. § 103 over Norling is also respectfully traversed. Applicant respectfully submits that claims 1, 2, 4-9, 11-13, 15-20 and 23-25 are not anticipated by nor obvious over Norling for the many reasons of record and for the following reasons.

Norling describes a controlled release unit in the form of a pellet, but he does not describe a compound particle for direct compression as the present invention. Just because Norling teaches controlled release does not mean that the structure of Norling's pellets is identical to the claimed invention.

*Norling
Teaches
The
Formulation*


Norling does not produce spray-dried pellets as stated by the Examiner. Norling is only employing spray-drying for producing the core of his pellets (column 3, lines 46-49, example 1A, 1B, 1C), which core is then coated in a fluidized bed apparatus (example 4). The cores consist mainly of an inorganic material such as calcium carbonate. The core can also contain a drug (example 3). The claims by Norling clearly specify that the final release formulation consists of "coated cores" (first sentence in claim 1). Thus, Norling discloses a very different structure than the large controlled release units of the present invention, which are produced by direct compression of the claimed compound particles (Figure 3).

Serial No. 09/319,541
December 4, 2001
Page 5

For these reasons, Norling cannot anticipate the claimed invention. Accordingly, withdrawal of the Section 102 rejection is respectfully requested.

In view of all of the objections and rejections of record having been addressed, it is believed that the present application is in condition for allowance and Notice to that effect is respectfully requested.

Respectfully submitted,
Manelli Denison & Selter, PLLC



Jeffrey S. Melcher
Reg. No. 35,950
Tel: 202.261.1000
Fax: 202.887.0336

Customer No. 20736